DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 12, 2014

Draeger Medical Systems, Inc.
Karen Provencher
Regulatory Affairs Manager
6 Tech Drive
Andover, Massachusetts 01810

Re: K141756
Trade/Device Name: Infinity Explorer
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MSX
Dated: October 7, 2014
Received: October 9, 2014

Dear Karen Provencher,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K141756

Device Name: Infinity Explorer

Indications for Use:

Infinity Explorer software enables the Patient Vicinity Workstation (PVW) to function as the secondary display for physiological parameters received from the primary Infinity modular monitors. Infinity Explorer displays only visual parameter alarm data for the connected modular monitor and does not generate audible alarms. Audible and visual alarms are available at the primary Infinity modular monitors.

The device is intended to be used in an environment where patient care is provided by healthcare professionals such as physicians, nurses, and technicians trained on the use of the device, who will determine when use of the device is indicated based upon their professional assessment of the patient's medical condition.

The device is intended for use with adult, pediatric, and neonatal populations.

MRI Compatibility Statement:
The Infinity Explorer is not compatible for use in a MRI magnetic field.

Contraindications:
There are no known contraindications.

Prescription Use __✓__ OR Over-The –Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K141756

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. Submitter:

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Regulatory Affairs Manager
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Date Prepared: December 3, 2014

II. Device Names / Common Names / Classification Names:

Trade Name:	Infinity Explorer
Common Name:	System Network and Communication Physiological Monitors
Classification Name:	System Network and Communication Physiological Monitors
Product Code:	MSX
Class:	II
Regulation Number:	21 CFR §870.2300

III. Identification of Predicate or Legally Marketed Devices:

Infinity Explorer cleared under K060254 on April 4, 2006

IV. Device Description:

The Infinity Explorer software runs on a specialized medical grade Patient Vicinity Workstation (PVW) and allows the user to extend the viewing capability of the bedside monitor and integrate additional patient information originating from various sources throughout the hospital on a single display. Additional patient information can reside remotely on a clinical information system, HIS, Web, Lab Department, etc.

Specifically, the Infinity Explorer software extends the real-time viewing capabilities of the primary patient monitors that are part of the Infinity modular monitoring series. Infinity Explorer software runs on a dedicated Infinity C700 for IT patient vicinity workstation. The workstation monitors are touch screen computer workstations that allow you to interact with menu functions. However, a keyboard and mouse may also be used to interact with the display. The patient connected bedside monitor is the primary monitoring device and the workstation monitor with Infinity Explorer software is the secondary display monitor. All data to and from the bedside patient monitor is transmitted to or received from Infinity Explorer software over the Infinity Network. Infinity Explorer software can also provide control back to the connected bedside patient

monitor. There are no audible alarms on the patient vicinity workstation running Infinity Explorer software. However, there are visual alarms initiated at the primary monitor that present on the workstation display running Infinity Explorer software.

V. Indications / Intended Use:

Infinity Explorer software enables the Patient Vicinity Workstation (PVW) to function as the secondary display for physiological parameters received from the primary Infinity modular monitors. Infinity Explorer displays only visual parameter alarm data for the connected modular monitor and does not generate audible alarms. Audible and visual alarms are available at the primary Infinity modular monitors.

The device is intended to be used in an environment where patient care is provided by healthcare professionals such as physicians, nurses, and technicians trained on the use of the device, who will determine when use of the device is indicated based upon their professional assessment of the patient's medical condition.

The device is intended for use with adult, pediatric, and neonatal populations.

MRI Compatibility Statement:
The Infinity Explorer is not compatible for use in a MRI magnetic field.

Contraindications:
There are no known contraindications.

VI. Comparison of Technological Characteristics with the Predicate Device:

The subject device Infinity Explorer software is a modification of the predicate device. The basic technological characteristics remain the same between the 2 versions of the device. The subject and predicate devices are based on the following same technological elements:

- Both versions of the Infinity Explore software run on specified medical grade cockpits
- Both devices interface with specified Draeger bedside monitors
- Both devices are compatible with specified 3rd party applications

The following technological differences exist between the subject and predicate devices:

- Operating System
- Compatibility with newer version of Patient Vicinity Workstation
- Compatibility with latest versions of 3rd party applications
- Newer version of Infinity Explorer software cannot display DICOM images
- Compatibility with latest versions of primary bedside monitors

VII. Performance Data:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility:
Not applicable – The Infinity Explorer is a software application and does not come into contact with the patient.

Sterilization:
Not applicable – The Infinity Explorer is a software application and does not require sterilization for use.

Electrical Safety & Electromagnetic Compatibility (EMC):
Electrical safety and EMC testing was performed on the Patient Vicinity Workstation (PVW) consisting of display, keyboard, mouse and power supply. The PVW complies with IEC 60601-1:2012 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance and IEC 60601-1-2:2007 – Medical Electrical Equipment General Requirements for Electrocompatibility.

Software Verification and Validation Testing:
Software verification and validation testing were conducted and documentation was provided as recommended by the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Alarm testing as it applies to a secondary monitor was also performed to support the partial compliance to IEC60601-1-8:2006 + A1:2012 "General Requirements for Basic Safety and Essential Performance – Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems." The software for this device was considered as a "major" level of concern, since the software device provides vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary.

Mechanical & Environmental Testing:
The Patient Vicinity Workstation (PVW) was tested for

- Functional testing to requirements
- Shock & vibration
- Environmental Controls
- Climatic and Thermal Testing

Animal Testing:

Not applicable – animal testing was not required to support substantial equivalence to the predicate device.

Clinical Studies:
Not applicable – clinical studies were not required to support substantial equivalence to the predicate device.

VIII. Conclusion:

The modified Infinity Explorer has been tested in accordance with applicable standards and internal design control procedures. The results of the bench testing performed provided sufficient evidence to determine that the modified Infinity Explorer software with upgraded operating system is as safe and effective as the predicate device for its intended use.